

## **Federal Rescheduling of Hydrocodone Combination Products: Frequently Asked Questions**

The U.S. Drug Enforcement Agency published a final rule in the Federal Register on August 22, 2014 concerning “[Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II](#)”. The following are questions that the Board anticipates receiving – based on questions frequently asked about past rescheduling of controlled substances.

**Q: To which products does this rule change apply?**

A: Hydrocodone has actually been listed in Schedule II since the federal Controlled Substance Act was passed in 1971. However, products containing combinations of hydrocodone and either isoquinolone alkaloids of opium or nonnarcotic ingredients were later placed into Schedule III. The term “hydrocodone combination product” refers to these products that have been in Schedule III. Actually, as of the date of the adoption of this final rule, *all* hydrocodone-containing products were in Schedule III – except for Zohydro ER, a product that contains only hydrocodone and that was therefore placed in Schedule II upon its approval in 2013.

**Q: When will the rule be in effect?**

A: October 6, 2014.

**Q: What are the requirements related to inventorying hydrocodone combination products?**

A: Per requirements in the federal Controlled Substances Act, a pharmacy must conduct an inventory of all hydrocodone-containing products on October 6, 2014. Pharmacies must maintain that inventory with all other controlled substance inventory records. In addition, MN Rules 6800.4600 states:

Each pharmacy located in this state shall maintain a perpetual inventory system for Schedule II controlled substances. The system shall be established in a manner that will provide total accountability in all aspects of Schedule II drug distribution. The inventory shall be reconciled with the actual inventory monthly and the reconciliations shall be documented. Reconciliation documentation shall be retained for at least two years.

Consequently, pharmacies located within Minnesota must include hydrocodone combination products in their Schedule II perpetual inventory effective October 6, 2014.

**Q: Are prescriptions for hydrocodone combination products that are issued before October 6, 2014 valid after that date?**

A: According to the final rule: “Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with 21 CFR 1306.22-1306.23, 1306.25, and 1306.27, if such dispensing occurs before April 8, 2015.”

In plain language, any prescriptions for hydrocodone combination products that were issued before October 6, 2014 can continue to be handled as Schedule III prescriptions. Any refills remaining as of that date can be dispensed – but there can only be a total of five refills within six months from the date the prescription was issued.

In addition, the federal rules pertaining to the partial filling and transfer of Schedule III prescriptions between pharmacies apply. So does the rule regarding the provision of Schedule III prescription information between retail pharmacies and central fill pharmacies.

**Q: How should prescriptions for hydrocodone combination products that are issued on or after October 6, 2014 be handled?**

A: According to the final rule: “All prescriptions for HCPs must comply with 21 U.S.C. 829(a) and must be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of October 6, 2014. No prescription for HCPs issued on or after October 6, 2014 shall authorize any refills.”

In plain language, they must be handled as any other Schedule II controlled substance prescription would be handled. No refills are allowed, prescriptions cannot be transferred between pharmacies, paper prescriptions must be manually signed by the prescriber and electronic prescriptions must meet all of the requirements for controlled substance electronic prescriptions. Prescriptions may be faxed or partially filled only in those limited circumstances that are allowed by the federal rules.

**Q: When will I have to start using DEA Form 222 or CSOS to order hydrocodone combination products?**

A: October 6, 2014.

**Q: Can I use a manufacturer’s stock bottle for a hydrocodone combination product after October 6, 2014 if it is still labeled “C III”?**

A: Yes. Neither manufacturers nor pharmacies are required to relabel stock bottles of hydrocodone combination products that were distributed before October 6, 2014. However, stock bottles you receive on or after that date should be labeled “C II”.